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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,731	02/19/2008	Bakulesh Mafatlal Khamar	43939-00106	8375

26486 7590 04/14/2011  
BURNS & LEVINSON, LLP  
125 SUMMER STREET  
BOSTON, MA 02110

EXAMINER
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SWARTZ, RODNEY P

ART UNIT	PAPER NUMBER
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1645

NOTIFICATION DATE	DELIVERY MODE
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04/14/2011

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@burnslev.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/583,731	KHAMAR ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rodney P. Swartz, Ph.D.	1645	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10February2011.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21,23,24 and 29 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-21 is/are allowed.
- 6) ☒ Claim(s) 23,24 and 29 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1645

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 10 February 2011, is acknowledged.

Claims 23, 24 and 29 have been amended.

2. Claims 1-21, 23, 24 and 29 are pending and under consideration.

### **Rejections Maintained**

3. The rejection of claims 23 and 24 under 35 U.S.C. 112, first paragraph, scope of enablement for composition of *Mycobacterium w* and an unidentified antigen which prevent all diseases in mammals (claim 23) or decrease morbidity and mortality associated with all disease (claim 24), is maintained for reasons of record.

Applicants argue that the amendments to the claims to recite "specific to the incorporated antigen" obviates the rejection. Applicants cite several references to support the argument by showing that adjuvants are compounds that enhance the specific immune response against co-inoculated antigens and also give examples of antigens.

The examiner has considered applicants' argument, in light of the cited references, but does not find it persuasive.

As newly amended, claim 23 remains drawn to a composition comprising a pharmaceutically effective amount of the composition as claimed in claim 1 sufficient to prevent diseases in mammal specific to the incorporated antigen.

As newly amended, claim 24 is drawn to a composition containing a pharmaceutically effective amount of the composition as claimed in claim 1 sufficient to decrease morbidity and mortality associated with disease specific to an incorporated antigen.

The claims remain drawn to a composition of *Mycobacterium w* and an antigen to prevent all diseases in mammals (claim 23) or decrease morbidity and mortality associated with

Art Unit: 1645

all diseases (claim 24), wherein said antigen is specific to "an" incorporated antigen (claim 24) or "the" incorporated antigen (claim 23).

The scope of claim 23 is extremely broad in that the claim recites that any composition of claim 1 containing any antigen is sufficient to prevent diseases in mammal "specific to the incorporated antigen". However, the specification has not shown that all antigens when placed in a composition with *Mycobacterium w* and/or constituents thereof, now have the capability of preventing all disease specific to the incorporated antigen, even if the art concerning this antigen is either silent to this capability or has actually shown that the antigen does not have this capability by itself or with other adjuvants.

The same lack of support concerns claim 24 whose scope is a composition sufficient to decrease morbidity and mortality of all diseases wherein said composition comprises *Mycobacterium w* and/or constituents thereof and "an" incorporated antigen. In this claim amendment, the antigen of the composition of claim 1 is not required to be the same as the qualifier in claim 24 as the recitation is not "specific to the incorporated antigen", but "an incorporated antigen".

4. The rejection of claim 29 under 35 U.S.C. 102(b) as being anticipated by Bakulesh et al (WO02/056898A2, 25 July 2002), is maintained for reasons of record.

As newly amended, claim 29 does not state that the "incorporated" antigen be different from the recited *Mycobacterium w* and/or a constituent thereof. Thus, the claim still reads on a composition of one component, i.e., *Mycobacterium w*, as taught by Bakulesh et al.

### **Rejection Necessitated by Amendment**

#### **Claim Rejections - 35 USC § 112**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1645

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Newly amended claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As newly amended, the claim is unclear if "an incorporated antigen" is the same as or "the antigen" of claim 1.

### **Conclusion**

6. Claims 23, 24, and 29 are finally rejected.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday-Thursday from 7:30 AM to 6:00 PM EST.

Art Unit: 1645

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's Supervisor, Gary Nickol, at (571)272-0835.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rodney P. Swartz, Ph.D./

Primary Examiner, Art Unit 1645

April 11, 2011